



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

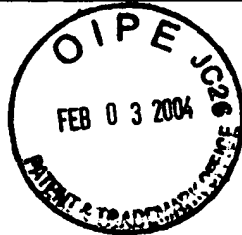
Applicant(s): Kostenuik, et al.

Serial No.: 09/843,221

Filed: April 26, 2001

For: Modulators of Receptors for Parathyroid Hormone  
and Parathyroid Hormone-Related Protein

Docket No.: A-665B



Group Art Unit No.: 1647

Examiner: Christopher J. Nichols, Ph.D.

INFORMATION DISCLOSURE STATEMENT  
BEFORE  
MAILING DATE OF EITHER A FINAL ACTION OR NOTICE  
OF ALLOWANCE (37 CFR 1.97(c))

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Under the guidelines of 37 CFR 1.97, applicants submit a copy of each of the references listed on the attached supplemental PTO-1449 (Modified) form for consideration by the Examiner.

This Information Disclosure Statement is being filed after three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last, but **before** the mailing date of either:

- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,  
whichever occurs first.

**STATEMENT OR FEE**

Accompanying this transmittal is:

A ☐ a statement as specified in 37 CFR 1.97(e):

**STATEMENT**

I, the person(s) signing below state:

**EXPRESS MAIL CERTIFICATE**

"Express Mail" mail labeling number: EV 352489168 US

Date of Deposit: February 3, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Joy C. Nichols  
Printed Name

[Signature]  
Signature

- ☐ that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 CFR 1.97(e)(1).

OR

- ☐ that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 CFR 1.97(e)(2).

OR

- B. ☒ the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00).

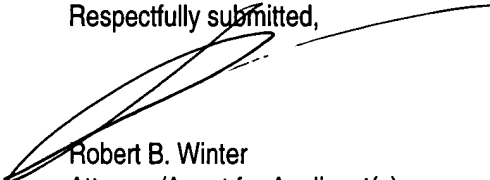
Applicant(s) request(s) consideration of this information and passage of the application to issue.

#### FEE PAYMENT

Please charge Deposit Account No. 01-0519 in the amount of \$180.00 (37 CFR 1.97(c)). An original and one copy are enclosed.

The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account No. 01-0519.

Respectfully submitted,

  
Robert B. Winter  
Attorney/Agent for Applicant(s)  
Registration No.: 34,458  
Phone: (805) 447-2425  
Date: February 3, 2004

Please send all future correspondence to:

US Patent Operations/RBW  
Dept. 4300, M/S 27-4-A  
AMGEN INC.  
One Amgen Center Drive  
Thousand Oaks, California 91320-1799



Modified Form PTO-1449  <b>LIST OF REFERENCES CITED BY APPLICANT</b>  (Use several sheets if necessary)	Atty. Docket No.	Serial No.
	A-665B	09/843.221
	Applicant	
	Kostenuik, et al.	
	Filing Date	Group
	April 26, 2001	1647

**U.S. PATENT DOCUMENTS**

EXAMINER'S INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A1	5,693,616	02 Dec 1997	Krstenansky et al.			
	A2	5,807,823	15 Sep 1998	Krstenansky et al.			
	A3	5,874,086	23 Feb 1999	Krstenansky et al.			
	A4	6,417,333 B1	09 Jul 2002	Bringhurst et al.			
	A5						
	A6						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
							YES	NO
	B1							
	B2							

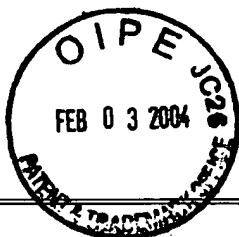
**OTHER DOCUMENTS (Including Publisher, Author, Title, Date, Pertinent Pages, Etc.)**

C1	Baumann et al., Response of Cortical Bone to Antiresorptive Agents and Parathyroid Hormone in Aged Ovariectomized Rats. BONE, 16(6): 247-253. (Feb 1995).
C2	Berning et al., Tibolone and its effects on bone: a review. CLIMACTERIC, 4(2):120-136. (June 2001).
C3	Crandall, C., Parathyroid Hormone for Treatment of Osteoporosis. ARCHIVES OF INTERNAL MEDICINE, 162: 2297-2309. (11 Nov 2002).
C4	Hodsman, A. B. et al., Biochemical responses to sequential human parathyroid hormone (1-38) and calcitonin in osteoporotic patients. BONE AND MINERAL., 9(2): 137-152. (May 1990)
C5	Hofbauer, L. C. et al., Stimulation of Osteoprotegerin Ligand and Inhibition of Osteoprotegerin Production by Glucocorticoids in Human Osteoblastic Lineage Cells: Potential Paracrine Mechanisms of Glucocorticoid-Induced Osteoporosis. ENDOCRINOLOGY, 140(10): 4382-4389. (Oct 1999)
C6	Kostenuik, P. J. et al., OPG and PTH(1-34) Have Additive Effects on Bone Density and Mechanical Strength in Osteopenic Ovariectomized Rats. ENDOCRINOLOGY, 142(10): 4295-4304. (Oct 2001)
C7	Li, M. et al., Parathyroid Hormone Monotherapy and cotherapy with Antiresorptive Agents Restore Vertebral Bone Mass and Strength in Aged Ovariectomized Rates. BONE, 16(6): 629-635. (Jun 1995)
C8	Morley, P. et al., Parathyroid Hormone: An Anabolic Treatment for Osteoporosis. CURRENT PHARMACEUTICAL DESIGN, 7(8): 671-687. (May 2001).
C9	Reeve, J. et al., Treatment with parathyroid peptides and estrogen replacement for severe postmenopausal vertebral osteoporosis: prediction of long-term responses in spine and femur. J. BONE MINR. METAB., 19(2): 102-114. (09 March 2001).

EXAMINER:

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Sheet 2 Of 2

<b>Modified Form PTO-1449</b>  <b>LIST OF REFERENCES CITED BY APPLICANT</b>  (Use several sheets if necessary)	Atty. Docket No.	Serial No.
	A-665B	09/843.221
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	Filing Date	Group
	April 26, 2001	1647

EXAMINER'S  
INITIALS**OTHER DOCUMENTS (Including Publisher, Author, Title, Date, Pertinent Pages, Etc.)**

	C10	Rosen et al., CLINICAL REVIEW 123: HOT TOPIC Anabolic Therapy for Osteoporosis. THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM, 86(3): 957-964, (Mar 2001).
	C11	Tanizawa et al., Effects of human PTH (1-34) and bisphosphonate on the osteopenic rat model. TOXICOLOGY LETTERS. 102-103: 399-403, (Dec 1998).
	C12	Wronski, T. J., et al., Parathyroid Hormone is More Effective Than Estrogen or Bisphosphonates for Restoration of Lost Bone Mass in Ovariectomized Rats. ENDOCRINOLOGY, 132(2): 823-831, (Feb 1993)
	C11	
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